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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/224,683	ZSEBO ET AL.
	Examiner	Art Unit
	Bridget E. Bunner	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 05 May 2003 (Paper No. 18) has been entered in full. Claim 71 is amended and claim 115 is added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 71-115 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The rejection of claim 71 under 35 U.S.C. § 101 (for reading on a product of nature) as set forth at pg 3 of the previous Office Action (Paper No. 16, 29 November 2002) is *withdrawn* in view of the amended claim (Paper No. 18, 05 May 2003).

2. The rejection of claims 71-78 under obviousness-type double patenting as set forth at pg 3-4 of the previous Office Action (Paper No. 16, 29 November 2002) is *withdrawn* in view of the abandonment of case 09/643,652.

3. The rejection of claims 71-74 and 76 under 35 U.S.C. § 112, first paragraph (enablement) as set forth at pg 4-12 of the previous Office Action (Paper No. 16, 29 November 2002) is *withdrawn* in view of the amended claims (Paper No. 18, 05 May 2003).

4. The supplemental information disclosure statement filed on 05 May 2003 (Paper No. 18) has been considered.

Specification

5. The objection to the specification regarding sequence compliance, priority, the Brief Description of Drawings, and references to other patent applications is maintained and held in abeyance until all other issues are resolved (see Office Action of 20 July 2001, Paper No. 9).

However, Applicant is encouraged to submit the appropriate corrections at Applicant's earliest convenience so that the Examiner can approve of the corrections.

Double Patenting

6. The rejection of claims 71-115 under obviousness-type double patenting as being unpatentable over claims in U.S. Patent No. 6,204,363 at pg 2-4 of the Office Action of 20 July 2001 (Paper No. 9) is maintained and held in abeyance until an executed terminal disclaimer is filed. It is noted to Applicant that newly filed claim 115 has been added to this rejection for the same reasons of record.

New Claim Objection

7. Claim 115 is objected to because of the following informalities:

The word "the" is missing before the word "sequences" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 75 and 77-115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a therapeutically effective amount of an isolated SCF polypeptide comprising at least 130 amino acids of the amino acid sequence of SEQ ID NOs: 46, 61, or 63 (Figures 15C, 42A-C, and 44A-C) that enhances hematopoiesis, does not reasonably provide enablement for the SCF polypeptide consisting of the amino acid sequence as set out as 1-100, 1-110, 1-120, 1-123, 1-127, as set out in Figures 42A-C and 44A-C or for an analog of SCF polypeptide of any of the sequences set forth in SEQ ID NO: 46, 61, or 63 that possesses an activity associated with SCF. The specification is also enabling for a SCF composition that is effective to treat hematopoietic disorders, but not epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, or germ

cell disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pg 4-12 of the previous Office Action (Paper No. 16, 29 November 2002), pg 3-7 of the Office Action of 20 March 2002 (Paper No. 12) and pg 5-9 of the Office Action of 20 July 2001 (Paper No. 9).

Specifically, the claims recite a SCF composition wherein the SCF polypeptide is selected from the group of polypeptides consisting of the amino acid sequence set out as 1-100, 1-110, 1-120, 1-123, 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-566, 1-157, 1-158, 1-158, 1-159, 1-160, 1-161, 1-163, 1-164, 1-165, 1-166, 1-168, 1-174, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-220, and 1-128 as set out in Figures 15C, 42A-C, and 44A-C. The claims also recite that the amount of SCF in the composition is effective to treat hematopoietic disorders, epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders. The claims are also directed to a composition which comprises a therapeutically effective amount of an analog of stem cell factor (SCF) polypeptide of any of the sequences set forth in SEQ ID NO: 46, SEQ ID NO: 61, or SEQ ID NO: 63 that possess an activity associated with SCF and one or more cytokines in a pharmaceutically acceptable carrier.

Applicant's arguments (Paper No. 18, 05 May 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant asserts that the enablement requirements of the statute are satisfied when the specification, disclosure, taken with the teachings in the art, teaches an effective process for making and using the claimed compositions from known starting materials, and the specification describes methods of using the claimed compositions (*Ex parte Gasteambide, Thal, Rohracj, and*

Laroche, 189 USPQ 643,645 (PTO Bd. App. 1974). Applicant indicates that all that is required is that Applicant objectively enable the claimed invention. Applicant states that the law has never required that the Applicant provide specific working examples. Applicant submits that the experimentation required for the instant application is nothing more than mere routine.

Applicant's arguments have been fully considered but are not found to be persuasive. The fact patterns of *Ex parte Gasteambide, Thal, Rohracj, and Laroche* as cited by the Applicant and of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant rejections. The 35 U.S.C. § 112 enablement requirement in *Ex parte Gasteambide, Thal, Rohracj, and Laroche* was satisfied in that the specification, taken with prior art, teaches an effective process for making claimed compounds from corresponding *known* steroids and describes method of using them for disclosed treatment of a condition. Although the specification in the instant application teaches art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current, *previously unknown* invention as a starting point for further experimentation. The skilled artisan must resort to trial and error experimentation to generate the infinite number of SCF analogs and SCF fragments smaller than 130 amino acids of SEQ ID NOs: 46, 61, or 63, as recited in the claims and to screen them for a desired activity. Such trial and error is considered undue. Additionally, undue experimentation would also be required of the skilled artisan to determine the biological activity that is associated with the claimed SCF derivatives.

(ii) Applicant indicates that MPEP § 2164.01(b) provides specific examples in the case law of decisions ruling that the disclosure was either non-enabling (*In re Wright*, 999 F .2d 1557, 27

USPQ2d 1510 (Fed. Circ. 1993) and *In re Goodman*, 11 F. 3d 1046, 29 USPG2d 2010 (Fed. Circ. 1993)) or enabling (*In re Wands* and *In re Bundy*, 642 F .2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981)). Applicant argues that in both *In re Wright* and in *In re Goodman,* there was specific evidence that cast doubt on the scope of the claimed invention. Applicant submits that such is not the case here. Applicant states that stem cell factor is not a diverse and complicated genus and full length SCF is a protein having 248 amino acids. Applicant indicates that the teachings of the specification exemplify numerous SCF fragment sequences that have activities associated with the full length SCF sequences and method of determining the SCF activity of other fragments that one skill in the art could easily generate. Applicant asserts that one the SCF sequence is known, those of skill in the art can readily make fragments because, much like making hybridomas that was in question in *In re Wands*, the techniques for generating fragments of a protein sequence are well known to those of skill in the art. Applicant submits that the mere fact that a large number of fragments could be generated does not preclude enablement.

Applicant's arguments have been fully considered but are not found to be persuasive. Again, although the specification in the instant application teaches art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active SCF derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The skilled artisan must resort to trial and error experimentation to generate the infinite number of SCF analogs and SCF fragments smaller than 130 amino acids of SEQ ID NOs: 46, 61, or 63, as recited in the claims and to screen them for a desired activity. Such trial and error is considered undue. Additionally, undue experimentation would also be required of the skilled artisan to determine the biological activity that is associated with the claimed SCF derivatives.

(iii) Applicant asserts that while pg 185 of the specification teaches that some SCF fragments have a reduced specific activity, it is a wrong to state that fragments less than 1-130 have no SCF activity. Applicant points out that the specification teaches that fragments 2-164 and 5-164 of SCF still possess some SCF-related activity.

Applicant's arguments have been fully considered but are not found to be persuasive. The Examiner is not stating that all SCF fragments shorter 130 amino acids of SEQ ID NOs: 46, 61, and 63 have no activity. The Examiner is simply indicating that the specification of the instant application is silent with respect to the activity of any fragments shorter than 130 amino acids of SEQ ID NOs: 46, 61, or 63. Undue experimentation would be required of the skilled artisan to determine if all SCF analogs and fragments less than 130 amino acids have any activity

(iv) Applicant asserts that structures of numerous SCF polypeptide are taught in the specification. Applicant states that the Examiner has cited two generalized texts that postulate that certain regions of a protein may be less tolerant to mutation that others. Applicant contends that the Examiner has not pointed to any specific teaching the art that one of skill in the art would be unable to produce analogs of the proteins of the present invention, i.e., analogs of SCF proteins. Applicant mentions that the Examiners in *In re Wright* and *In re Goodman* utilized pre- and post-filing date references to show that the claims were not enabled. Applicant argues that numerous working examples of sequences of SCF polypeptides are taught in the present application, and based on that disclosure it would be a matter of routine experimentation to mutate the sequences to generate analogs in the scope of the claimed invention. Applicant submits that there is no credible reason for suggesting that screening a recombinant protein for a

desired SCF activity would require undue experimentation when the Federal Circuit has clearly admonished that the screening of numerous hybridomas would not required undue experimentation (*In re Wands*). Applicant contends that as seen from the data in the specification at pg 182-185, Applicant has repeated the entire screening process for SCF analogs no less than 32 separate analogs.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's assertion that the claimed SCF analogs and SCF fragments comprising less than 130 amino acids of SEQ ID NOs: 46, 61, or 63 have biological activities similar to known full length SCF cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide mutations which alter the normal activity of the polypeptide. For example, Wuyts et al. (J Immunol 163: 6155-6163, 1999) establishes that NH_2-and COOH-terminal truncations of granulocyte chemotactic protein-2 (GCP-2) have enhanced neutrophil chemotactic potency as compared to wild-type GCP-2 (abstract; pg 6157-6158). Sher et al. (J Biol Chem 274(49):35016-35022, 1999) disclose that keratinocyte growth factor (FGF-7) acts predominantly on cells of epithelial origin and regulates processes in embryonal and adult development, including cell growth, differentiation, cell migration, and repair of epithelial tissues (pg 35016, ¶ 1). Sher et al. demonstrate that point mutations in a loop of FGF-7 do not alter receptor binding affinity, but cause reduced mitogenic potency and reduced ability to induce receptor-mediated phosphorylation events (pg 35020-35021). Additionally, a SCF mutant called $Steel^{17H}$ (Sl^{17H}) induces melanocyte defects and sterility in males. The Sl^{17H} allele contains a mutation that results in the substitution of 36 amino acids in the SCF cytoplasmic domain with 28 novel amino acids (Kapur et al., Blood 94(6): 1915-1925, 1999). Kapur et al. teach that compound heterozygous Sl/Sl^{17H} mice manifest several hematopoietic abnormalities in

vivo, such as red blood cell deficiency, bone marrow hyperplasia, and defective thymopoiesis (pg 1917-1918; Figures 2-3). In vitro, both the soluble and membrane-associated Sl^{17H} isoforms exhibit reduced cell surface expression on stromal cells and diminished biological activity as compared to wild soluble and membrane-associated forms (abstract, pg 1919-1921; Figures 6-7). Finally, Kopchick et al. (U.S. Patent 5,350,836) disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (2000, Genome Research 10:398-400) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (1998, Trends in Genetics 14:248-250) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in underpredictions of functionality of a new protein and (2) overpredictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith et al. (1997, Nature Biotechnology 15:1222-1223) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene.

Therefore, based on the discussions above concerning the specific examples of structurally similar proteins that have different functions, along with the art's recognition that one cannot rely upon structural similarity alone to determine functionality, the specification fails to teach the skilled artisan how to use the claimed analogs and fragments to make biologically active SCF without resorting to undue experimentation to determine what the specific biological activities of the analogs and fragments are.

Furthermore, although the specification in the instant application teaches art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active SCF derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The skilled artisan must resort to trial and error experimentation to generate the infinite number of SCF analogs and SCF fragments smaller than 130 amino acids of SEQ ID NOs: 46, 61, or 63, as recited in the claims and to screen them for a desired activity. Such trial and error is considered undue. Please note that Applicant's argument of a "large quantity of experimentation" is only one factor to be considered under a 35 U.S.C. § 112, first paragraph, enablement rejection.

(v) Applicant asserts that the term "central role in embryogenesis and hematopoiesis" and "capacity for treatment of various stem cell deficiencies" are express teachings found in the specification (pg 18, lines 20-24). Applicant contends that there is no reason to doubt that the pharmaceutical compositions of the present invention possess the activity attributed to them by Applicant. Applicant submits that the fact that a specific working example of the treatment of each of the disorders is not present in the specification does not defeat the enablement of the claimed invention. Applicant states that optimal dosage, duration, and mode of administration

are parameters that a physician may readily determine on a case-specific basis. Applicant also cites post-filing date references that indicate SCF increases melanocyte proliferation, differentiation, survival, chemotaxis, secretion, and accumulation *in vivo* (Kawakami et al., J. Invest. Dermatol 114: 471-478, 2002). Costa et. (J Exp Med 183(6): 2681-2686, 1996) teach that SCF compositions promote hyperplasia and functional activation of human mast cells and melanocytes *in vivo*. Corti et al. (Exp Neurol 177(2): 443-452, 2002) disclose that SCF administration modulates the availability of GFP+ cells in the brain and enhances their capacity to acquire neuronal characteristics.

Applicant's arguments have been fully considered but are not found to be persuasive. Again, it is noted that the recitation of a SCF composition effective to treat epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders is interpreted as an intended use. The specification does not disclose any methods or working examples of administering any SCF/cytokine composition to treat any disorder other than a hematopoietic disorder. The Examiner has interpreted claims 81-90 to mean that all possible epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders are to be treated with SCF and SCF fragments and analogs. Therefore, such conditions or diseases that are encompassed by the claims include Incontinentia Pigmenti, Alzheimer's disease, Parkinson's disease, and various cancers, among others, which have proven to be recalcitrant to treatment in the art. However, the specification of the instant application does not teach any methods or working examples that indicate SCF or SCF analogs and fragments are able to treat all possible epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders. Although Applicant has cited several references demonstrating SCF activity *in vivo*, these references do not disclose treatment of any

diseases. Undue experimentation would still be required of one skilled in the art to determine the efficacy of treatment of numerous diseases after administration of the SCF/cytokine composition. The specification also does not teach the skilled artisan the optimal dosage, duration, and mode of administration of the composition comprising a SCF polypeptide/cytokine. Furthermore, the claimed composition may not necessarily treat epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, or germ cell disorders. Such trial and error experimentation is considered undue.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to generate the infinite number of SCF "analogs" or SCG fragments shorter than 130 amino acids as recited in the claims, to determine the specific activity of a polypeptide analog or fragment, and to determine the efficacy of treatment of disorders other than hematopoietic disorders, the lack of direction/guidance presented in the specification regarding which structural features that are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

9. Claims 75 and 77-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The basis for this rejection is set forth for claims 71-114 at pg 13-14 of the previous Office Action (Paper No. 16, 29 November 2002), pg 8-10 of the Office Action of 20 March 2002 (Paper No. 12) and pg 9-11 of the Office Action of 20 July 2001 (Paper No. 9).

Specifically, the claims recite a SCF composition wherein the SCF polypeptide is selected from the group of polypeptides consisting of the amino acid sequence set out as 1-100, 1-110, 1-120, 1-123, 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-566, 1-157, 1-158, 1-158, 1-159, 1-160, 1-161, 1-163, 1-164, 1-165, 1-166, 1-168, 1-174, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-220, and 1-128 as set out in Figures 15C, 42A-C, and 44A-C. The claims also recite that the amount of SCF in the composition is effective to treat hematopoietic disorders, epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders. The claims are also directed to a composition which comprises a therapeutically effective amount of an analog of stem cell factor (SCF) polypeptide of any of the sequences set forth in SEQ ID NO: 46, SEQ ID NO: 61, or SEQ ID NO: 63 that possess an activity associated with SCF and one or more cytokines in a pharmaceutically acceptable carrier.

Applicant's arguments (Paper No. 18, 05 May 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that the specification exemplifies at least 32 analogs/fragments of the SCF, in addition, full SCF sequences are presented in SEQ ID NOs: 46, 61, and 63. Applicant deduces that the specification teaches at least 35 specific sequences. Applicant contends that they have met the burden of showing possession of the genus encompassed by the claims by providing the examples at pg 182-185 of the specification. Applicant argues that the

specification provides a detailed description of representative SCF sequences encompassed by the claims, the specification teaches those of skill how to make variants of those sequences, and therefore show possession of the claimed invention. Applicant believes that recent decisions of the Federal Circuit support this contention (*Moba v. Diamond Automation* and *Enzo Biochem, Inc. v. Gen-probe, Inc.*, 63 USPQ2d 1609, 1628 (Fed. Cir. 2002).

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has not provided evidence to demonstrate that the skilled artisan would be able to envision the detailed structure of the infinite number of SCF analogs or SCF fragments with all possible biological activities recited in the claims. The scope of the claims include numerous structural variants. Although the specification discloses the structure and function of numerous SCF fragments, these descriptions are not a representative number to support the description of an entire genus of functionally equivalent SCF biologically active fragments or analogs, which incorporate all SCF mutants, derivatives, and fragments. Therefore, only a human SCF fragment that enhances hematopoiesis and wherein the human SCF polypeptide consisting of the amino acid sequence of 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-162, 1-163, 1-164, 1-165, 1-166, 1-168, 1-173, 1-178, 1-180, 1-183, 1-185, 1-188, 1-189, 1-220, and 1-248 of SEQ ID NOs: 46, 61, and 63, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Furthermore, the fact pattern of the cases cited by the Applicant and of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant rejections. Specifically, the decision in *Moba B.V. v. Diamond Automation Inc.* (egg sorting method) indicates that compliance with written description requirement of 35 U.S.C. §112 does not require a particular form of disclosure, provided person of skill in art could

determine from specification that inventor possessed invention at time of filing. However, in the instant application, the skilled artisan cannot determine from the specification that Applicant had in possession at the time of filing, the structure and function of the infinite number of SCF analogs and SCF fragments shorter than 130 amino acids recited in the claims. Also, regarding the decision of *Enzo Biochem, Inc. v. Gen-probe, Inc.*, the Federal Circuit has indicated that functional description of genetic material may be sufficient to satisfy written description requirement of 35 U.S.C. §112. The written description requirement can be met by showing that the invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, including functional characteristics when coupled with known or disclosed correlation between function and structure. Although the instant application is claiming a SCF polypeptide composition, the specification has not identified the structural and functional characteristics of all possible SCF analogs and SCF fragments shorter than 130 amino acids.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 71-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The term "an activity associated with SCF" in claims 71-115 is a relative term which renders the claims indefinite. The term "an activity associated with SCF" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is inappropriate to read limitations in the specification into the claims. The claims must

independently define the invention for which patent protection is sought. It is suggested to Applicant that the claims be amended to recite "...or SEQ ID NO: 63 that enhances hematopoiesis".

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C Kemmerer

BEB
Art Unit 1647
July 23, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER